FEB 10 2005

Date: February 1, 2005

510(k) SUMMARY

SUBMITTED BY:	Becton Dickinson and Company 7 Loveton Circle Sparks, MD 21152 Phone 410-316-4206 Fax: 410-316-4499
CONTACT NAME:	Bradford M. Spring, Manager, Regulatory Affairs
DATE PREPARED:	February 1, 2005
DEVICE TRADE NAME:	GEMIFLOXACIN 5µg, BBL™ Sensi-Disc™ Antimicrobial Susceptibility Test Disks
DEVICE COMMON NAME:	Antimicrobial Susceptibility Test Disks
DEVICE CLASSIFICATION:	21 CFR§866.1620, Class II (Product Code JTN), Susceptibility Test Disks, Antimicrobial
PREDICATE DEVICE:	Other BBL™ Sensi-Disc™ (eg, Ciprofloxacin 5 µg, BBL™ Sensi-Disc™)

INTENDED USE:

Antimicrobial Susceptibility Test Disks are used for semi-quantitative *in vitro* susceptibility testing by standardized agar diffusion test procedures. Gemifloxacin 5 µg BBL™ Sensi-Disc™ is intended for use in determining the susceptibility to Gemifloxacin of a wide range of bacteria, as described in the "Indications for Use" section. Zone sizes used for interpretation of tests, including control organism limits, were determined by the antimicrobic manufacturer and received FDA approval under NDA Number 21-158.

DEVICE DESCRIPTION:

Gemifloxacin 5µg BBL™ Sensi-Disc™ is prepared by impregnating high quality paper with accurately determined amounts of Gemifloxacin supplied by the drug manufacturer. Each Gemifloxacin disk is clearly marked on both sides with the agent and drug content. Gemifloxacin cartridges each contain 50 impregnated disks that are packed as either a single cartridge in a single box, or in a package containing ten cartridges. Gemifloxacin disks are used for semi-quantitative *in vitro* susceptibility evaluations by the agar diffusion test method.

Agar diffusion susceptibility methods employing dried filter paper disks impregnated with specific concentrations of antimicrobial agents were developed in the 1940s. In order to eliminate or minimize variability in the testing, Bauer et al. developed a standardized procedure in which Mueller Hinton Agar was selected as the test medium.

Various regulatory agencies and standards-writing organizations subsequently published standardized reference procedures based on the Bauer-Kirby method. Among the earliest and most widely accepted of these standardized procedures were those published by the U.S. Food and Drug Administration (FDA) and the World Health Organization (WHO). The procedure was adopted as a consensus standard by the National Committee for Clinical Laboratory Standards (NCCLS) and is periodically updated.

DEVICE PRINCIPLE:

Disks containing a wide variety of antimicrobial agents are applied to the surface of Mueller Hinton Agar plates [or Haemophilus Test Medium Agar for *Haemophilus influenzae* or Mueller Hinton Agar with 5% Sheep Blood for *Streptococcus* species] inoculated with pure cultures of clinical isolates. Following incubation, the plates are examined and the zones of inhibition surrounding the disks are measured and compared with established zone size ranges for individual antimicrobial agents in order to determine the agent(s) most suitable for use in antimicrobial therapy. The categorical interpretation [susceptible (S), intermediate (I), or resistant (R)] for the organism being tested with the antimicrobial agent is made by comparing zone diameters to those found in the respective organism tables of NCCLS Document M2 ("Performance Standards for Antimicrobial Disk Susceptibility Tests) and of NCCLS Document M100 ("Performance Standards for Antimicrobial Susceptibility Testing").

DEVICE COMPARISON:

The BBL™ Sensi-Disc™ Antimicrobial Susceptibility Test Disks - Gemifloxacin 5µg is similar to the BBL™ Sensi-Disc™ Antimicrobial Susceptibility Test Disks - Ciprofloxacin 5 µg in that:

- Both methods are for antimicrobial susceptibility testing using paper disks impregnated with an antimicrobial agent.
- Both methods have the same intended use.
- Both methods provide the user with antimicrobic minimum inhibitory concentration (MIC) results based on measurements of zone diameters.
- Both methods require the user to determine categorical interpretations (S/I/R) using the measured zone diameters against NCCLS Approved Standards M2 and M100.
- Both methods use pure cultures of bacterial isolates.

The BBL™ Sensi-Disc™ Antimicrobial Susceptibility Test Disks - Gemifloxacin 5µg differs from the BBL™ Sensi-Disc™ Antimicrobial Susceptibility Test Disks - Ciprofloxacin 5 µg in that:

- BBL™ Sensi-Disc™ Antimicrobial Susceptibility Test Disks - Gemifloxacin 5µg is a susceptibility test that uses disks impregnated with the antimicrobic Gemifloxacin at a concentration of 5µg while the BBL™ Sensi-Disc™ Antimicrobial Susceptibility Test Disks - Ciprofloxacin 5 µg is a susceptibility test that uses disks impregnated with the antimicrobic Ciprofloxacin at a concentration of 5 µg.
- BBL™ Sensi-Disc™ Antimicrobial Susceptibility Test Disk - Gemifloxacin 5 µg is a susceptibility test used to test a different battery of microorganisms than the BBL™ Sensi-Disc™ Antimicrobial Susceptibility Test Disk - Ciprofloxacin 5 µg.

SUBSTANTIAL EQUIVALENCE TESTING DATA:

See the Gemifloxacin drug package insert, "Susceptibility Tests: Diffusion Techniques".

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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Mr. Bradford M. Spring
Manager, Regulatory Affairs
BD Diagnostics Systems
Becton, Dickinson and Company
7 Loveton Circle
Sparks, MD 21152

Re: k050062
Trade/Device Name: BBL™ Sensi-Disc™ Antimicrobial Susceptibility Test Disks, Gemifloxacin 5 µg
Regulation Number: 21 CFR 866.1620
Regulation Name: Antimicrobial Susceptibility Test Disks
Regulatory Class: Class II
Product Code: JTN
Dated: January 5, 2005
Received: January 11, 2005

Dear Mr. Spring:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (240)276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K050062

Device Name: BBL™ Sensi-Disc™ Antimicrobial Susceptibility Test Disks, Gemifloxacin 5µg

Indications for Use:

Use of Gemifloxacin 5µg, BBL™ Sensi-Disc™ for *in vitro* agar diffusion susceptibility testing is indicated when there is a need to determine the susceptibility of bacteria to Gemifloxacin. 5µg has been shown to be active *in vitro* against most strains of microorganisms listed below, as described in the FDA approved drug insert for this antimicrobic.

Active *In Vitro* and in clinical infections against:

Aerobic gram-positive microorganisms
Streptococcus pneumoniae (including multidrug resistant strains)
Aerobic gram-negative microorganisms
Haemophilus influenzae
Haemophilus parainfluenzae
Klebsiella pneumoniae (many strains are only moderately susceptible)

Active *In Vitro* Against:

Aerobic gram-positive microorganisms
Staphylococcus aureus (methicillin-susceptible strains only)
Streptococcus pyogenes

Aerobic gram-negative microorganisms
Acinetobacter lwoffi
Klebsiella oxytoca
Proteus vulgaris

Prescription Use _X_ (Per 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (Per 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K050062